

IFW

Practitioner's Docket No. U 014533-9

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application  
of

Inventor(s)

for

Title of invention

**OR**

In re application of: K. Chandrashekhar, et al.

Serial No.: 10/817,306

Group No.:

Filed: April 2, 2004

Examiner:

For: NOVEL CAPSULE FORMULATIONS OF ETOPOSIDE FOR ORAL USE

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))**

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\***

- ☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"  
Mailing Label No. \_\_\_\_\_ (**mandatory**)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office

Date: MAY 27, 2004

Signature

JANET L. CORD

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
- (4) *Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

**WARNING:** *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

**NOTE:** *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

## **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

**NOTE:** *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*

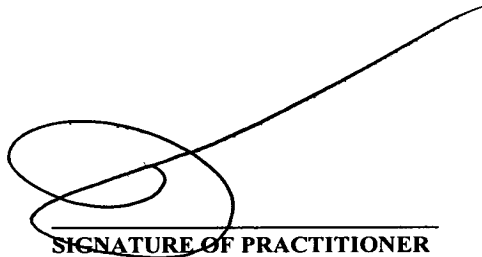
**NOTE:** *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** *"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

If a fee is required, please charge deposit account 12-0425.



**SIGNATURE OF PRACTITIONER**

Reg. No. 33778

Tel. No.: (212) 708-1935

Customer No.: 00140

JANET I. CORD  
(type or print name of practitioner)

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: K. Chandrashekhhar, et al.

Serial No.: 10/817,306

Group No.: -

Filed: April 2, 2004

Examiner.: -

For: NOVEL CAPSULE FORMULATIONS OF ETOPOSIDE FOR ORAL USE

Attorney Docket No.: U 014533-9

**Assistant Commissioner for Patents**  
**Washington, D.C. 20231**

Sir:

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached references which are also listed on the attached Form PTO-1449.

Respectfully submitted,

  
\_\_\_\_\_  
JANET I. CORD  
LADAS & PARRY  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NY 10023  
REG. NO.: 33778 (212) 708-1935

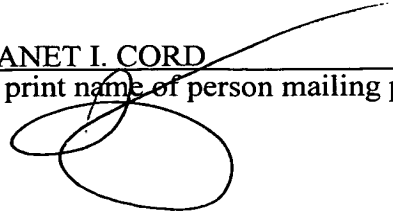
---

**CERTIFICATE OF MAILING (37 CFR 1.8a)**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231

JANET I. CORD  
(Type or print name of person mailing paper)

Date: May 27, 2004

  
\_\_\_\_\_  
(Signature of person mailing paper)

FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

SERIAL NO.

U 014533-9

10/817,306

APPLICANT

K. CHANDRASHEKHAR ET AL.

FILING DATE

GROUP

04/02/2004

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,280,770	08/2001	Pather et al.	
	AB	6,309,665	10/2001	Barthelemy et al.	
	AC	6,312,704	11/2001	Farah et al.	
	AD	2003/0022944	01/2003	Gumkowski et al.	
	AE	5,929,030	07/1999	Hamied et al.	
	AF	5,399,363	03/1995	Liversidge et al.	
	AG	4,713,246	12/1987	Begum et al.	
	AH	4,772,589	09/1988	Kaplan et al.	
	AI	4,734,284	03/1988	Terada et al.	
	AJ	6,054,136	04/2000	Farah et al.	
	AK	5,993,858	11/1999	Crison et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	02/076938	10/2002	WO		
	AM	02/076937	10/2002	WO		
	AN	02/076970	10/2002	WO		
	AO	02/102354	12/2002	WO		
	AP	02/102376	12/2002	WO		
	AQ	02/083177	10/2002	WO		
	AR	95/27492	10/1995	WO		
	AS	03/017986	03/2003	WO		
	AT	02/056878	07/2002	WO		
	AU	01/78724	10/2001	WO		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AV

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014533-9

10/817,306

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

APPLICANT

K. CHANDRASHEKHAR ET AL.

(Use several sheets if necessary)

FILING DATE

GROUP

04/02/2004

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,458,373	10/2002	Lambert et al.	
	AB	5,968,987	10/1999	Charman et al.	
	AC	20020107250	08/2002	Hariharan et al.	
	AD	20030045563	03/2003	Gao et al.	
	AE	20030021844	01/2003	Barthelemy et al.	
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	00/09093	02/2000	WO		
	AM	02/24172	03/2002	WO		
	AN	03/000295	01/2003	WO		
	AO	0754045	03/2002	EP		
	AP	1058540	10/2001	EP		X
	AQ					
	AR					
	AS					
	AT					
	AU					

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AV	English translation of claims of EP 1058540, dated October 31, 2001
--	----	---

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014533-9

10/817,306

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

APPLICANT

K. CHANDRASHEKHAR ET AL.

FILING DATE

GROUP

04/02/2004

(Use several sheets if necessary)

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,280,770	08/2001	Pather et al.	
	AB	6,309,665	10/2001	Barthelemy et al.	
	AC	6,312,704	11/2001	Farah et al.	
	AD	2003/0022944	01/2003	Gumkowski et al.	
	AE	5,929,030	07/1999	Hamied et al.	
	AF	5,399,363	03/1995	Liversidge et al.	
	AG	4,713,246	12/1987	Begum et al.	
	AH	4,772,589	09/1988	Kaplan et al.	
	AI	4,734,284	03/1988	Terada et al.	
	AJ	6,054,136	04/2000	Farah et al.	
	AK	5,993,858	11/1999	Crison et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	02/076938	10/2002	WO		
	AM	02/076937	10/2002	WO		
	AN	02/076970	10/2002	WO		
	AO	02/102354	12/2002	WO		
	AP	02/102376	12/2002	WO		
	AQ	02/083177	10/2002	WO		
	AR	95/27492	10/1995	WO		
	AS	03/017986	03/2003	WO		
	AT	02/056878	07/2002	WO		
	AU	01/78724	10/2001	WO		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AV

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014533-9

10/817,306

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

APPLICANT

K. CHANDRASHEKHAR ET AL.

(Use several sheets if necessary)

FILING DATE

GROUP

04/02/2004

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,458,373	10/2002	Lambert et al.	
	AB	5,968,987	10/1999	Charman et al.	
	AC	20020107250	08/2002	Hariharan et al.	
	AD	20030045563	03/2003	Gao et al.	
	AE	20030021844	01/2003	Barthelemy et al.	
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	00/09093	02/2000	WO		
	AM	02/24172	03/2002	WO		
	AN	03/000295	01/2003	WO		
	AO	0754045	03/2002	EP		
	AP	1058540	10/2001	EP		X
	AQ					
	AR					
	AS					
	AT					
	AU					

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AV	English translation of claims of EP 1058540, dated October 31, 2001
--	----	---

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.